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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,998	08/18/2003	John D. Hatlestad	GUID.058PA	2963

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EXAMINER	
CRABTREE, JOSHUA DAVID	
ART UNIT	PAPER NUMBER
3714	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/642,998	HATLESTAD ET AL.	
	Examiner	Art Unit	
	Joshua D. Crabtree	3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 35-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 35-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the amendment dated 12/26/2006; Claims 15-34 and 57-96 have been cancelled. Claims 1-14 and 35-56 are pending.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14 remain rejected under 35 U.S.C. 101 as being directed toward non-statutory subject matter. Specifically, claims 1-14 are directed toward the result of collecting data. Although the claimed structure fulfills result of the intended claimed invention (i.e., collecting sleep data), there is no utility for using the collected data. The claims merely recite collecting data, but not include any implementation of the data to achieve utility. In addition, the steps of "detecting" and "collecting" do not provide any "useful, tangible, and concrete result", as required under 35 U.S.C. 101. Therefore, rejection under 35 U.S.C. 101 stands, and is proper.

The applicant's argument with regard to the previous rejection of claims 35-56 under 35 U.S.C. 101 are persuasive. Therefore, the previous rejection of claims 35-56 under 35 U.S.C. 101 is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 5, and 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. (US 6,641,542) in view of Sullivan et al. (US 5,245,995).

With regard to claims 1 and 35, Cho et al. disclose detecting physiological conditions associated with sleep quality (Col. 4: 29-33). With regard to detecting non-physiological conditions, Cho et al. disclose measuring the sleep time of the patient (Col. 9: 9-19). The applicant has listed sleep time as a non-physiological condition in Table 2, on page 6 of the specification. However, Cho et al. do not explicitly disclose measuring a non-physiological condition, other than time, comprising an ambient condition external to the patient that affects sleep quality, as recited in the claim. Sullivan et al. teach that it is known in the art to detect ambient conditions such as background noises, as part of a method of detecting sleep apnea (Col. 3: 3-13). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Sullivan et al. into the invention of Cho et al. in order to provide a method which detects time, along with other non-physiological conditions, such as background noise, which might affect sleep quality. Such data as background

noise would affect a person's sleep, and therefore it would be advantageous to detect such data in a system used to detect and treat a sleep disorder.

With regard to the limitation of collecting sleep quality data based on the detected conditions, using an implantable device, Cho et al. disclose this feature (Col. 5: 5-25).

With regard to claim 35, and the limitation wherein at least one of collecting and evaluating the sleep quality is performed by an implantable device, Cho et al. disclose this feature (Col. 5: 5-25).

With regard to claim 2, and the limitation of detecting a cardiovascular condition, Cho et al. disclose detecting hypertension (Col. 4: 53-65).

With regard to claim 3, Cho et al. disclose detecting respiratory conditions, such as Cheyne-Stokes respiration (Col. 6: 61-65).

With regard to claim 5, and the limitation of detecting a blood chemistry condition, Cho et al. disclose detecting oxygen saturation in the blood (Col. 8: 3-20).

With regard to claims 7 and 8, Cho et al. do not disclose detecting an environmental condition (as in claim 7) or contextual condition (as in claim 8). Sullivan et al. teach the feature of detecting background noise, as previously described. It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Sullivan et al. into the invention of Cho et al. in order to provide a system in which environmental conditions are monitored when diagnosing sleep apnea.

With regard to claims 9 and 37, and the limitation of collecting data associated with sleep stages, Cho et al. disclose measuring sleep cycle length (Col. 3: 14-17), and measuring eye movement to determine if the patient has reached the REM stage of sleep (Col. 2: 21-23).

With regard to claims 10 and 38, and the limitation of collecting data associated with sleep disruption, Cho et al. disclose detecting abnormal arouses (Col. 6: 57-65).

With regard to claims 11 and 39, and the limitation of collecting data associated with disordered breathing, Cho et al. disclose detecting apneas and hypopneas (Col. 8: 46-60).

With regard to claims 12 and 40, and the limitation of collecting data associated with a movement disorder, Cho et al. disclose measuring limb movements (Col. 6: 53-65).

With regard to claim 13, and the limitation of storing the collected sleep quality data, Cho et al. disclose storing the data (Col. 5: 35-38).

With regard to claim 14, and the limitation of transmitting the collected sleep quality data, Cho et al. disclose that the data may be transmitted (Col. 8: 38-45).

With regard to claim 36, and the limitation wherein the collecting and evaluating of sleep data are performed at least in part implantably, Cho et al. disclose that the evaluation can be performed by the processor, which is part of the implantable device (Col. 9: 56-60).

With regard to claim 41, and the limitation wherein evaluating the sleep quality comprises determining one or more metrics associated with sleep quality, Cho et al. disclose gathering metrics associated with sleep apnea (Col. 3-24-38).

With regard to claim 42, and the limitation wherein evaluating the sleep quality comprises trending one or more metrics associated with sleep quality over time, Cho et al. disclose determining the number of apneas experienced per hour (Col. 8: 46-60).

With regard to claim 43, and the limitation wherein evaluating sleep quality comprises determining one or more metrics associated with disordered breathing, Cho et al. disclose measuring breathing cycles (Col. 3: 13-23).

With regard to claim 44, and the limitation wherein evaluating sleep quality comprises determining one or more metrics associated with movement disorders, Cho et al. disclose measuring limb movements (Col. 6: 52-65).

With regard to claim 45, and the limitation wherein evaluating sleep quality comprises determining one or more composite metrics based on metrics associated with sleep and metrics associated with events that disrupt sleep, Cho et al. disclose that a combination of factors is used to determine whether a patient has sleep apnea (Col. 2: 18-29; Col. 9: 9-20). .

With regard to claim 46, Cho et al. disclose transmitting sleep quality data and the sleep quality evaluation to a separate device (Col. 8: 39-45).

4. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cho et al. in view of Sullivan et al., as applied above, and further in view of Kallok et al. (US

5,146,918). Cho et al., as modified by Sullivan et al., do not explicitly disclose detecting a nervous system condition. Kallok et al. teach detecting central nervous system inspiratory drive to the respiratory muscles to detect apnea. Kallok et al. that lack of nerve activity can be an indicator of apnea (Col. 2: 4-24). It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the teaching of Kallok et al. into the invention of Cho et al., as modified by Sullivan et al., in order to provide a system in which nervous system conditions are monitored to detect sleep apnea.

5. Claims 47-56 are rejected under the same grounds as presented in the previous office action.

Response to Arguments

6. Applicant's arguments with respect to claims 1-14 and 35-46 have been considered but are moot in view of the new ground(s) of rejection.

7. Applicant has argued, with regard to claims 47-56 (pp. 11-13), that the combination of Cho and Lindenthaler does not provide a reasonable expectation of success, and that neither Cho nor Lindenthaler suggest the desirability of such a combination. The examiner respectfully disagrees. Cho discloses a method for detecting and treating sleep apnea (See Abstract). Lindenthaler teaches a method for diagnosing sleep apnea (See Abstract). With regard to the argument regarding expectation of success, both the inventions of Cho and Lindenthaler involve diagnosing sleep apnea in

a human. It would be reasonable to assume that the muscle condition detection, as taught by Lindenthaler, would also work in the method of Cho, since both inventions are used with a human. In other words, so long as the human subject being treated with the invention of Cho has muscles to detect, then it follows that the person's muscle conditions could be detected, as taught by Lindenthaler, with reasonable success.

With regard to the argument regarding motivation to combine the references, since Lindenthaler teaches that the step of detecting muscle conditions is important in diagnosing apnea, it would be desirable to incorporate this feature into an invention, such as Cho, which detects and treats sleep apnea. Both the methods of Cho and Lindenthaler have the similar goal of detecting sleep apnea. One of ordinary skill in the art would be strongly motivated to combine the teachings of two methods, such as Cho and Lindenthaler, which are both directed to diagnosing sleep apnea. As stated in the previous office action, Lindenthaler specifically teaches that muscle conditions are an important factor in causing sleep apnea (Col. 1: 15-30). Therefore, Lindenthaler provides motivation to implement such a feature in a method for diagnosing sleep apnea.

With regard to the argument that the combination of Cho and Lindenthaler would be inoperable, the examiner respectfully disagrees. As stated above, both Cho and Lindenthaler teach methods which may be used to diagnose sleep apnea. So long as the human subject being treated with the invention of Cho has muscles, then the conditions of those muscles may be detected, as taught by Lindenthaler. Detecting the muscle conditions, as taught by Lindenthaler, would not render the method of Cho

inoperable, since such a procedure could be implemented as part of the method of Cho. As part of a method to diagnose sleep apnea, it would have been reasonable to expect that muscle condition detection, as taught by Lindenthaler, would be advantageous to implement in the method of Cho.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joshua D. Crabtree whose telephone number is 571-272-8962. The examiner can normally be reached on 8:00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC
Joshua D. Crabtree
March 6, 2007

Joe H. Cheng
Primary Examiner